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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 1998

WARNING LETTER

Mr. Soren Olesen, Managing Director
Pinol Finmekanik A/S
Engvej 33
Gorlose DK-3330
DENMARK

Dear Mr. Olesen:

During an inspection of your firm located in Gorlose, Denmark on September 21-24, 1998, our investigator determined that your firm manufactures endosseous implants. These products are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformity with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation (copy enclosed), as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

820.198(a) Complaint files.

Failure to have adequate procedures for evaluating complaints, as required under 820.198(a).

For example, Pinol's complaint records document complaints of loose metal parts and oil contamination inside the endosseous implants. However, failure investigation of these complaints has not been documented. This is covered in Item #1 on the FDA 483 issued at the close of the inspection.

820.100(a)(1) Corrective and preventive action.

Failure to establish procedures for implementing corrective and preventive action and to analyze processes, work operations, complaints and quality records to identify existing and potential causes of nonconforming product or other quality problems, as required under 820.100(a)(1).

For example, quality data to include in-process rejects, incoming component rejects, complaint data, and product returns have not been documented in sufficient detail to detect or prevent recurring quality problems, as indicated in Item #8 of the FDA 483.

820.90(c ) Nonconforming product.

Failure to document rework and re-evaluation activities, as required in 820.90(c ).

For example, Items #2 and #9 on the FDA 483 state there were no records for endosseous implants returned to the firm for rework and redistribution.

820.80(d) Final acceptance activities.

Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria, as required under 820.80(d).

For example, Pinol's records do not document proof of inspection or check for loose metal parts, as a result of tooling problems. This was listed as Item #3 on the FDA 483. In addition, process specifications for the [redacted] (cleaning agent) and [redacted] cleaning process have not been defined, documented, or approved for use, as indicated in Item #5 on the FDA 483.

820.75 Process validation.

Failure to validate the [redacted] and [redacted] cleaning processes and the [redacted] welding process, as required under 820.75.

For example, the [redacted] and [redacted] cleaning processes have not been validated to assure adequate removal of manufacturing oil used during production, as listed in Item #4 on the FDA 483. Also, Item #10 points out that Pinol has not validated a formal adjustment/set up procedure to assure a consistent welding process.

820.70(a) Production and process controls.

Failure to establish and maintain process control procedures necessary to ensure conformance to specifications, as required under 820.70(a).

For example, Item #6 on the FDA 483 states that procedures for changing and testing of the [redacted] (cleaning agent) have not been approved and implemented; and, Item #10 states that the firm has not defined formal adjustment/set up procedures to assure a consistent welding process while preventing surface oxidation, surface cracks and surface penetration for a given type of metal.

820.86 Acceptance status.

Failure to maintain acceptance status throughout manufacturing to ensure that only product which has passed the required acceptance activities is distributed, as required under 820.86.

For example, Item #7 on the FDA 483 states deviations found in production records showed that components were approved and distributed without QC inspection, two lots of implants were approved for distribution without records of rework or reinspection, and components were inspected and released without documented sampling.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is Pinol's responsibility to ensure adherence to each requirement of the Act and its implementing regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Once Pinol submits a response to the FDA outlining the corrections made to address the FDA 483 observations and the date(s) of implementation, a review will be completed of that response and a determination made as to whether the corrections appear adequate.